CLAIMS

1. Use of a sphingoid-polyalkylamine conjugate for the preparation of a pharmaceutical composition for modulating the immune response of a subject.

2. The use according to Claim 1, wherein said sphingoid-polyalkylamine conjugate comprises a sphingoid backbone carrying, via a carbamoyl bond at least one polyalkylamine chain.

3. The use of Claim 1 or 2, wherein said modulation includes stimulation or enhancement of the immune response.

4. The use of any one of Claims 1 to 3, in combination with a biologically active molecule.

5. The use of Claim 4, wherein said biologically active molecule has, at a physiological pH, a net negative dipole moment or a net negative charge or contains at least one region having a net negative charge.

6. The use of Claim 4 or 5, wherein said biologically active molecule is an immunomodulating amino acid molecule, a nucleic acid molecule or a low molecular weight compound.

7. The use of Claim 6, wherein said biologically active molecule is an antigenic protein, antigenic peptide, antigenic polypeptide, carbohydrate or an immunostimulant.

8. The use of Claim 6, wherein said nucleic acid molecule is an oligodeoxynucleotides (ODN).

9. The use of any one of Claims 1 to 8, in combination with an immunostimulating agent.

10. The use of any one of Claims 1 to 9, wherein the sphingoid-polyalkylamine conjugate forms lipid assemblies.

11. The use of Claim 10, wherein said sphingoid- polyalkylamine conjugate forms vesicles, micelles or mixtures thereof.

12. The use of any one of Claims 1 to 11, wherein the sphingoid is selected from ceramide, dihydroceramide, phytoceramide, dihydrophytoceramide, ceramine, dihydroceramine, phytoceramine, dihydrophytoceramine.

13. The use of Claim 12, wherein said sphingoid is a ceramide.

14. The use of any one of Claims 1 to 13, wherein said polyalkylamine is selected from spermine, spermidine, a polyalkylamine analog or a combination of same thereof.

15. The use of any one of Claims 4 to 14, wherein said sphingoid-polyalkylamine conjugate is co-lyophilzed with the biologically active molecule, or said biologically active material is mixed with preformed sphingoid-polyalkylamine conjugate assemblies.

16. The use according to any one of Claims 1 to 15, wherein said sphingoid-polyalkyamine conjugate is N-palmitoyl D-erythro sphingosyl carbamoyl-spermine (CCS).

17. The use of any one of Claims 1 to 16, for the preparation of a vaccine.

18. The use of Claim 17, for the preparation of influenza vaccine.

19. The use of Claim 18, wherein said biologically active material is derived from influenza virus or an analog of a molecule derived from influenza virus.

20. The use of Claim 19, wherein said biologically active material is a combination of hemagglutinin and neuraminidase (HN).

21. The use of any one of Claims 1 to 20 for the preparation of intranasal or intramascular vaccination.

22. Use of N-palmitoyl D-erythro sphingosyl carbamoyl-spermine (CCS) for the preparation of a pharmaceutical composition for enhancing or stimulating an immune response of a subject to influenza virus.

23. A method for modulating the immune response of a subject, the method comprises providing said subject with a therapeutically effective amount of a sphingoid-polyalkylamine conjugate together with a biologically active molecule.

24. The method of Claim 23, wherein said sphingoid-polyalkylamine conjugate comprises a sphingoid backbone carrying, via a carbamoyl bond at least one polyalkylamine chain.

25. The method of Claim 23 or 24, wherein said modulation includes stimulation or enhancement of the immune response.

26. The method of any one of Claims 23 to 25, wherein said biologically active molecule is associated with said sphingoid-polyalkylamine conjugate.

27. The method of Claim 26, wherein said biologically active molecule has, at a physiological pH, a net negative dipole moment, a net negative charge or contains at least one region having a net negative charge.

28. The method of any one of Claims 23 to 27, wherein said biologically active molecule is an immunomodulator selected from a nucleic acid molecule, an amino acid molecule or a low molecular weight compound.

29. The method Claim 28, wherein said biologically active molecule is selected from an antigenic protein, antigenic peptide, antigenic polypeptide, or a carbohydrate.

30. The method Claim 28, wherein said nucleic acid molecule is an oligodeoxynucleotides (ODN).

31. The method of any one of Claims 23 to 30, comprising administering said sphingoid-polyalkylamine conjugate associated with a biologically active molecule, together with an immunostimulating agent.

32. The method of Claim 31, wherein said immunostimulating agent is administered concomitant with, or within a time interval before after administration of said sphingoid-polyalkylamine conjugate.

33. The method of any one of Claims 23 to 32, wherein said sphingoid-polyalkylamine conjugate forms a lipid assembly.

34. The method of Claim 33, wherein said lipid assembly comprises vesicles or micelles or combination of same.

35. The method of any one of Claims 23 to 34, wherein the sphingoid is selected from ceramide, dihydroceramide, phytoceramide, dihydrophytoceramide, ceramine, dihydroceramine, phytoceramine, dihydrophytoceramine.

36. The method of Claim 35, wherein said sphingoid is ceramide.

37. The method of any one of Claims 23 to 36, wherein said polyalkylamine is selected from spermine, spermidine, a polyamine analog or a combination of same thereof.

38. The method of any one of Claims 23 to 37, wherein said sphingoid-polyalkylamine conjugate is N-palmitoyl D-erythro sphingosyl carbamoyl-spermine (CCS).

39. The method of any one of Claims 23 to 38, wherein said biologically active material is derived from influenza virus or an analog of a molecule derived from influenza virus.

40. The method of Claim 39, wherein said biologically active material is a combination of hemagglutinin and neuraminidase (HN).

41. The method of any one of Claims 23 to 40, comprising intranasal or intramuscular administration of said conjugate.

42. A method for modulating the immune response of a subject to influenza virus, the method comprises providing said subject with N-palmitoyl D-erythro sphingosyl carbamoyl-spermine (CCS) together with an influenza antigen.

43. A pharmaceutical composition for modulating the immune response of a subject, the composition comprises: (i) at least one sphingoid-polyalkylamine conjugate; and (ii) at least one biologically active molecule.

44. The pharmaceutical composition of Claim 43, wherein said sphingoid-polyalkylamine conjugate comprises a sphingoid backbone carrying, via a carbamoyl bond at lest one polyalkylamine chain.

45. The composition of Claim 43 or 44, comprising at least one physiologically acceptable carrier.

46. The composition of any one of Claims 43 to 45, wherein said modulation includes stimulation or enhancement of the immune response.

47. The composition of any one of Claims 43 to 46, wherein said biologically active molecule has, at a physiological pH, a net negative dipole moment or a net negative charge or contains at least one region having a net negative charge.

48. The composition of any one of Claims 43 to 47, wherein said biologically active molecule is an immunomodulator selected from an amino acid molecule, a nucleic acid molecule, or a low molecular weight molecule.

49. The composition of Claim 48, wherein said biologically active molecule is selected from antigenic protein, antigenic peptide, antigenic polypeptide, or a carbohydrate.

50. The composition of Claim 48, wherein said nucleic acid molecule is an oligodeoxynucleotide (ODN).

51. The composition of any one of Claims 43 to 50, comprising an immunostimulating agent.

52. The composition of any one of Claims 43 to 51, wherein said sphingoid-polyalkylamine conjugate forms lipid assemblies.

53. The composition of Claim 52, wherein said sphingoid-polyalkylamine conjugate forms vesicles or micelles or combinations of same.

54. The composition of any one of Claims 43 to 53, wherein said sphingoid backbone is selected from ceramide, dihydroceramide, phytoceramide, dihydrophytoceramide, ceramine, dihydroceramine, phytoceramine, dihydrophytoceramine.

55. The composition of Claim 54, wherein said sphingoid is ceramide.

56. The composition of any one of Claims 43 to 55, wherein said polyalkylamine is selected from spermine, spermidine or a polyalkylamine analog of spermine or spermidine.

57. The composition of any one of Claims 43 to 56, wherein said sphingoid-polyalkylamine conjugate is N-palmitoyl D-erythro sphingosyl carbamoyl spermine (CCS).

58. The composition of any one of Claims 43 to 57, for vaccinating a subject against influenza virus.

59. The composition of Claim 58 wherein said biologically active molecule is derived from influenza virus or is an analog of a molecule derived from influenza virus.

60. The composition of Claim 59, wherein said biologically active molecule is a combination of hemagglutinin and neuraminidase (NH).

61. The composition of any one of Claims 43 to 60, in a dosage form suitable for intranasal or intramuscular administration.

62. A vaccine comprising N-palmitoyl D-erythro sphingosyl carbamoyl-spermine (CCS) in combination with hemagglutinin neuraminidase.

63. A complex comprising: (i) a sphingoid-polyalkylamine conjugate and (ii) a biologically active molecule capable of modulating an immune response of a subject.

64. The complex of Claim 63, wherein said sphingoid is linked, via a carbamoyl bond at lest one polyalkylamine chain.

65. The complex of Claim 63 or 64, wherein said biologically active molecule has at a physiological pH a net negative dipole moment or a net negative charge or contains at least one region having a net negative charge.

66. The complex of any one of Claims 63 to 65, wherein said biologically active molecule is an immunomodulator selected from an amino acid molecule, a nucleic acid molecule, or a low molecular weight molecule.

67. The complex of Claim 66, wherein said biologically active molecule is selected from an antigenic protein, antigenic peptide, antigenic polypeptide, or a carbohydrate.

68. The complex of Claim 66, wherein said nucleic acid molecule is an oligodeoxynucleotide (ODN).

69. The complex of any one of Claims 63 to 68, wherein said sphingoid-polyalkylamine conjugate forms lipid assemblies.

70. The complex of Claim 69, wherein said sphingoid-polyalkylamine conjugate forms vesicles or micelles or combinations of same.

71. The complex of any one of Claims 63 to 70, wherein said sphingoid is selected from ceramide, dihydroceramide, phytoceramide, dihydrophytoceramide, ceramine, dihydroceramine, phytoceramine, dihydrophytoceramine.

72. The complex of Claim 71, wherein said sphingoid is ceramide.

73. The complex of any one of Claims 63 to 71, wherein said polyalkylamine is selected from spermine, spermidine or a polyamine analog of spermine or spermidine.

74. The complex of any one of Claims 63 to 73, wherein said sphingoid-polyalkylamine conjugate is N-palmitoyl D-erythro sphingosyl carbamoyl spermine (CCS).

75. A kit for capturing a biologically active molecule, the kit comprises a sphingoid-polyalkylamine conjugate as defined in any one of Claims 1 to 22, and instructions for use of said conjugate as a capturing agent.